



UNITED STATES PATENT AND TRADEMARK OFFICE

[Signature]
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,668	03/10/2004	Hoi Shan Kwan	17329-002001 / 04F050US	4157
26161	7590	07/26/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			GOLDBERG, JEANINE ANNE	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,668

Applicant(s)

KWAN ET AL.

Examiner

Jeanine A. Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/12/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 16-28 and 42-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 29-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed May 12, 2006. Currently, claims 1-51 are pending. Claims 6-28, 34, and 39-51 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election with traverse of Group I, Claims 1-15, 29-41 in the paper filed May 12, 2006 is acknowledged.

The response picks the combination of SEQ ID NO: 9 and 13 to amplify the variable region. The response further asserts that SEQ ID NO: 9, 14-16 are not unrelated to one another. This argument has been thoroughly reviewed, but not persuasive because the primers hybridize to different variable regions of different plants.

Claims 6-28, 34, and 39-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed May 12, 2006.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 6-28, 34, and 39-51 drawn to an invention nonelected with traverse in the paper filed May 12, 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. This application claims priority to provisional application 60/453,842, filed March 10, 2003.

Drawings

4. The drawings are acceptable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-3, 29-31, 35, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US Pat. 6,309,840, October 30, 2001) in view of Honeycutt et al. (US Pat. 6,599,701, July 29, 2003).

Wang teaches PCR-RFLP test for the authentication of herbal Chinese medicines. Wang teaches the authentication of Chinese herbs had previously relied upon morphological and histological inspection. In many cases, such as in the authentication of *Acorus* species that method is unreliable. Wang thus teaches a method which relies upon the ITS1 and ITS2 which have lower homology across the plant kingdom (col. 1, lines 55-65). Wang analyzes the variations in different plant species within the ITS1 and ITS2 region as a means for authentication (col. 2, lines 1-5). Wang teaches plant DNA was isolated and the ITS regions of rDNA were selectively amplified using pairs of primers that correspond to the consensus DNA sequence within the rRNA. The authentication method taught by Wang requires the extraction of rDNA from a herb sample with known identity determined by traditional means (col. 5, lines 15-20). The ITS1 and ITS2 region are extracted using oligonucleotide primers that are conserved across the plant kingdom (col. 5, lines 20-25). Wang further teaches repeating the amplification for herbal samples to generating profiles from an authenticated sample. Wang teaches that the showing of similar profile with a known herb identifies the herbal material.

Wang does not specifically teach analyzing and comparing the known plants and unknown plants using dotting the DNA fragments on a solid support.

However, Honeycutt teaches identifying organisms by detecting differences among taxonomic groupings of organisms using solid supports. Honeycutt teaches that the regions may be analyzed in DNA of known organisms by a variety of nucleic acid detection methods (col. 4, lines 50-55). Wang teaches that where hybridization assays

of multiple target organism genomes are desired to be performed simultaneously using the same intronic region specific probes, it would be convenient to perform such hybridization probes in an array format (col. 16, lines 10-15). Wang teaches "after compilation of the intronic region profile for a given taxonomic group, the nucleotide sequences corresponding to the intronic regions of the different organisms belonging to the taxonomic group can be used in a microarray format on a microchip to perform simultaneous hybridization studies with various probes or sequences from unknown organisms (col. 16, lines 20-25). Moreover, Wang teaches "detecting the presence or absence of intronic regions can be accomplished by a variety of methods well known in the art for detecting nucleic acids. These include, for example, primer extension reactions, separation of amplified products by molecular weight, nucleotide sequencing, RFLP or hybridization with a specific nucleic acid probe" (col. 20, lines 60-65).

Therefore, it would have been *prima facie* obvious to the ordinary artisan at the time the invention was made to have modified the RFLP detection method of Wang with the array based method of Honeycutt for the expected benefits of high throughput analysis. Honeycutt teaches that analysis of multiple target organism genomes can be performed simultaneously using the same intronic region specific probes, it would be convenient to perform such hybridization probes in an array format (col. 16, lines 10-15). Honeycutt teaches that detecting the presence or absence of intronic regions can be accomplished by a variety of methods including RFLP or hybridization with a specific probe. The ordinary artisan would have been motivated to have modified the RFLP method of Wang to use the hybridization with a specific probe method of Honeycomb

for the specific reasons taught by Honeycomb including the ability to perform simultaneous analysis of multiple target organisms.

7. Claims 4, 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US Pat. 6,309,840, October 30, 2001) in view of Honeycutt et al. (US Pat. 6,599,701, July 29, 2003) as applied to claims 1-3, 29-31, 35, 37 above and further in view of <http://www.atihealthnet.com/pages/chineseherbsf2j.html>

Neither Wang nor Honeycutt teaches analysis of Ilex asprella.

However, the AIE Pharmaceuticals webpage clearly indicates that Ilex asprella is a Chinese herb.

Therefore, it would have been prima facie obvious to the ordinary artisan at the time the invention was made to analyze Ilex asprella, a well known Chinese herb for authentication. The ordinary artisan would have been motivated to test Ilex asprella, the Chinese herb since the prior art, namely Wang teaches the problems with authenticity of herbal Chinese medicines.

Conclusion

8. **No claims allowable over the art.**

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A) Carroll (US Publication 2002/0172945, November 21, 2002) teaches materials and methods for detection of pathogenic guignardia citricarpa and to

differentiate between pathogenic and non-pathogenic fungi associated with Citrus Black Spot disease. Carroll teaches differentiating between pathogenic and non-pathogenic species of *Guignardia* in Citrus isolates by obtaining DNA samples from citrus fruit suspected of being infected with *Guignardia*; contacting the fungal DNA with detectably labeled nucleic acid probes which bind pathogenic and non-pathogenic species of *Guignardia* specifically (para 8). Moreover Carroll teaches the DNA may be immobilized on a solid support (para 8). Carroll teaches that a pathogen-specific oligonucleotide probe may be immobilized on a solid matrix (para 10). A solid matrix is defined as filter paper, multiwell dishes, microchips and magnetic particles, for example (para 22). Carroll teaches the internal transcribed spacer ITS1 and ITS2 segments were studied (para 30).

B) Tooley et al. (US Pat 5,874,221, February 23, 1999) teaches species specific method for the PCR detection of phythophthora. Phythophthora species which infect potatoes may results in devastating disease potato late blight or in pink rot. The internal transcribed spacer region may be used to confirm the presence of the microorganisms or to distinguish among them (abstract).

C) Singh et al. (US Pat. 6,541,624, April 2003) teaches detecting the adulteration of loose as well as branded tea by any part of cashew plant and thus is part of a quality control measure.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

Art Unit: 1634

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.



Jeanine Goldberg

Primary Examiner

July 21, 2006